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DuPont Dow elastomers

February 14, 2005

Mr. Arthur L. Williams, Director
Louisville Metro Air Pollution Control District
850 Barrett Avenue
Louisville, KY 40204

Re: Formal Comments on STAR Program

Dear Mr. Williams:

DuPont Dow Elastomers appreciates the opportunity to comment on this set of proposed regulations.

The DuPont Dow facility (and DuPont before 1996) has been operating in west Louisville manufacturing Neoprene (polychloroprene) rubber since the early 1940's, when it was a government-owned plant. The facility currently has approximately 250 full-time employees and an average of around 55 contractors. The facility has a Title V operating permit and operates in compliance with that permit.

DuPont Dow maintains high standards for the conduct of its operations in compliance with environmental regulations. DuPont Dow is committed to protecting employees, communities and the environment. Our goal is to continually reduce air emissions of chloroprene.

DuPont Dow supports the objective of clean air in Louisville. DuPont Dow has participated with the District in all voluntary emission reduction programs sponsored by the District. While DuPont supports the general goals of risk reduction, DuPont Dow believes that the draft regulations are much broader than necessary, propose inappropriate, arbitrary, and scientifically unsupportable methodologies, and unfairly target the sources of a small percentage of community risk as currently drafted.

DuPont Dow believes that these proposed regulations, as they apply to chloroprene, propose methodologies that exaggerate potential hazards and impose standards that are not only much more conservative than are technically justified but also make compliance virtually impossible even with extremely low emissions.

During the operation of the Louisville Plant, DuPont and DuPont Dow have conducted and participated in a number of studies to ensure that employee workplace exposure to chloroprene did not cause adverse health effects. These studies are summarized below:

- Industry-sponsored toxicology studies conducted in the 1970's concluded that chloroprene monomer was not carcinogenic to animals.

- Standard epidemiology surveillance of DuPont's and DuPont Dow's U. S. employees, conducted approximately every 5 years during the period 1970 to the present, has not demonstrated an increase in employee cancer mortality.

- In contrast, in 1996, chronic toxicity studies by the National Toxicology Program showed that chloroprene was carcinogenic to some rodents, specifically rats and mice.

- An industry-sponsored multinational epidemiology study of chloroprene workers conducted by researchers at two universities is nearing completion. It is expected to confirm conclusions of earlier U.S. studies that found no correlation between chloroprene exposure and cancer mortality in humans.

- An industry-sponsored mechanistic study completed in 2003 was conducted to explore differences in chloroprene metabolism between animals and humans. The results of this study showed that humans are less sensitive to chloroprene than the rodents used in the NTP study. These results supplement the recent epidemiology study, which indicated that humans are unlikely to develop cancer at chloroprene exposure levels experienced in industrial settings. Exposure levels for the general population are much lower than in industrial settings.

- The results to date of the epidemiology study indicate that chloroprene workers have lower overall rates of both cancer and non-cancer mortality than the general population.

Any classification of chloroprene and subsequent setting of BAC_C for chloroprene must take full account of the information resulting from these studies.

We are very disappointed by the process the District chose to develop these regulations. Hurried in-house development by the District without openness excluded a true stakeholder process that would have allowed extensive input from the regulated community. This has produced overly complex regulations with unclear objectives and confusing and conflicting requirements. A collaborative process could have produced a much better set of regulations, with clear intent, broadly understood requirements, and a minimum of non-value-adding requirements. The meetings held by the District were held at a superficial level of interaction that prevented the interactions that could have corrected most of these issues before the hasty proposal. Instead, the District has chosen a closed process that encouraged adversarial positions.

For these reasons, DuPont Dow does not support these proposed regulations in their current form. We believe that the District needs to withdraw these proposed regulations and, through an orderly stakeholder process, develop regulations that have clear objectives, establish understandable and consistent requirements, and fairly address all areas of community risk.

We have attached extensive comments, both general and specific, that point out areas of issues and some examples of the points that make these regulations unacceptable. The specifics should be viewed as representative of issues but not totally comprehensive because of the time limitations in the comment period. We propose alternate methodologies to improve the regulatory approach and specific requirements to focus on risk reduction. To the extent applicable to the DuPont Dow facility, we also incorporate by reference comments submitted by GLI, AIK, LCP, and ACC...

We request an additional 30-60 day comment period to complete additional detailed comments.

Again, thank you for the opportunity to comment.

Sincerely,

DUPONT DOW ELASTOMERS L. L. C.

Robert F. Singleton

Robert F. Singleton
Unit Manager

RFS:be

Attachment

General Comments

Major Concerns

These regulations create standards and goals that are inappropriate and unrealistic. The methodology for determining a benchmark ambient concentration for chloroprene uses an inappropriate screening methodology and results in potential chemical risks for chloroprene being grossly overstated. Even with emissions reduced to insignificant levels, preliminary modeling using the proposed standard has indicated that achieving the standard would be virtually unattainable.

These regulations are overly broad and ambitious. The District has not established a sound scientific justification for this regulatory approach and these specific regulations. The regulations constitute a complicated and burdensome regulatory scheme that goes far beyond risk reduction. The regulations cover far more chemicals than the 18 indicated as contributing to significant community risk. By setting numerous requirements that are extremely burdensome, the regulations significantly raise the capital and operating costs for the regulated community. The overall regulatory approach is arbitrary and capricious.

These regulations are being promulgated without any estimate of impact on community air quality or health. The public and the media have focused on potential risks from chemical plants and ignored much higher known risks from other sources. The District has encouraged the impression that these regulations address risk broadly and will result in significant community risk improvement. We believe this is an unreasonable expectation. Actual community health improvements resulting from these regulations are expected to be insignificant. We believe the public will be disappointed by the results, and excess money and efforts will have been incurred without benefit to the community.

The regulations target the regulated community by setting extremely conservative standards and imposing very aggressive timelines. We believe it is poor public policy and an abuse of the District's mandate to focus on extreme standards for one regulated sector while ignoring others that impose greater community risk. These regulations address only a small portion of risk and ignore the majority of community risks, many of which have much more impact on the public. Many of these other areas of risk are not addressed at all or will not be addressed until much later under the proposed regulatory scheme.

The Regulatory Impact Assessment performed by the District far underestimates the burden, cost, and impacts of these regulations on the regulated community. For DuPont Dow Elastomers, as estimated in 2004, the minimum capital cost of the next potential emission reduction would be $35,000 per ton. Additional emission reduction projects approach $150,000 per ton. Both values far exceed those used in the Preliminary Regulatory Impact Assessment issued by the District. There has been no analysis of the ongoing cost and effort impacts on the regulated community. The combination of high capital requirements and high ongoing cost will have the effect of making chemical

manufacturing in Louisville much more costly than other locales, rendering industry non-competitive.

These regulations create unreasonable and extreme demands for reporting and duplication of efforts, often with no environmental benefit. Increasing demands are being placed on industry resources as companies attempt to remain cost-competitive.

The District has been unwilling to collaborate meaningfully with regulated stakeholders on the requirements in the regulations. These regulations were developed internally at the District. There was no participation from or dialog with the regulated community to develop consensus on tailoring requirements so that District objectives could be met with minimum impact, cost and effort. Meetings held by the District were primarily to explain the regulations and defend the approach, rather than to gain meaningful input. The District made only minor changes to the regulations that did not resolve the fundamental concerns.

As a result of inadequate collaboration, the regulations are poorly drafted. They are therefore unclear and/or conflicting in many of their requirements.

Many parts of the regulations are not supported by sound science. These areas will be addressed with detailed comments on each specific regulation.

Other Concerns

The District has not considered the impact of these regulations on their ability to issue permits in a timely manner or conduct their other business. We believe that these regulations, if enacted, will exacerbate current problems with timely issue of construction permits because of complex, unclear, and conflicting requirements. Predictable, prompt issuance of these permits is key to the regulated community for making necessary changes to upgrade or build new facilities in order to maintain business competitiveness. The District needs to prioritize their efforts more effectively, working in areas that produce true risk reduction.

These regulations subvert the risk assessment and risk management process begun by the WJCCTF West Louisville Air Monitoring Study. A detailed Risk Management process was developed, envisioning a stakeholder process to target opportunities and set goals for reducing community risk. The District circumvented this process, jumping immediately to the regulatory approach rather than utilizing the community-based collaborative Risk Management process.

The breadth and detailed requirements of the regulations will result in significant unintended consequences to many small and intermediate businesses. The requirements within the regulations are difficult for trained professionals to understand. Many smaller businesses will not realize that they will have significant requirements imposed upon them by these regulations.

Proposed Regulations 1.02, 1.06, and 1.21

1. The proposed regulations, as drafted, are overbroad and vague, and impose unreasonable requirements on the regulated community. For example, the proposed regulations inappropriately convert lists of alternative, mutually exclusive choices into sets of conflicting mandatory requirements.

   In numerous instances, the District uses "and" instead of "or" to link a list of alternatives, thus making all of the list entries mandatory. For instance, in proposed Regulation 1.21, Version 1, Draft #2 – Proposed, dated January 10, 2005, the conjunction "and" appears at the end of section 5.2.1.3 (line 181). Based on this word choice, a facility installing a pump, compressor, or agitator on or after July 1, 2006, pursuant to proposed § 5.2, will have to provide an "acceptable shaft sealing system" meeting all of the four criteria specified in § 5.2.1. To be "acceptable," the affected facility would normally expect to be able to choose one of the four alternatives listed in §§ 5.2.1.1 through 5.2.1.4. However, the District's wording appears to deny the intended effect of selecting among comparable alternatives, and makes all four "choices" into mandatory engineering requirements at an increase in cost without any increase in environmental benefit.

   The alternatives should be clearly indicated as choices as follows:

   5.2.1.1 A seal equipped with piping capable of transporting any leakage from the seal back to the process unit,
   5.2.1.2 A seal with a closed-vent system capable of transporting to a control device any leakage from the seal,
   5.2.1.3 A dual seal system with a heavy liquid or non-organic compound barrier fluid or gas at a higher pressure than the process pressure, **[OR]**
   5.2.1.4 A seal with an automatic seal failure detection and alarm system.

   These alternatives should be mutually exclusive. Selection of any one of them would accomplish the desired goal of eliminating or controlling the fugitive emissions from the newly installed equipment. In addition, during the federal rulemaking efforts in the early 1990's U.S. EPA recognized that there are legitimate product quality reasons supporting choices of pump seals other than a dual mechanical seal with pressurized barrier fluid. For systems with such product quality concerns, the set of mutually exclusive alternatives provides ample opportunities for compliance. However, by incorporating the word "and", the resulting list of mandatory requirements poses insurmountable difficulties.

   A second example is the definition of "Reference Method" in Regulation 1.02, Version 11, Draft #2 – Proposed, dated January 10, 2005. The definition is a longstanding one that illustrates the pervasiveness of unclear drafting. The definition specifies a list of federal regulations, including New Source Performance Standards (NSPS); National Emission Standards for Hazardous Air Pollutants (NESHAPs);

National Ambient Air Quality Standards (NAAQS); and State Implementation Plan (SIP) requirements. [Emphasis supplied.] The phrase "any one of" is absent from the text of this definition, as is the alternative conjunction "or". As a result, the number of reference methods that meets this all-encompassing definition is zero. If the definition instead specified "any method of sampling and analyzing for an air pollutant as prescribed in [any one of] the following EPA regulations: ...", the definition would convey the meaning presumably intended. In the absence of such clarity, the District's proposed regulations fail to provide fair notice to the regulated community.

In a third example, also taken from the proposed amended version of Regulation 1.02, the harm is equally apparent. The definition of "Process" at line 221 introduces its list of examples with a short sentence reading "Examples of a "process" include any of the following:" The subsections containing the examples follow this sentence. The next-to-last example is separated from the last example by the word "and". The proper conjunction remains "or".

A fourth and final example is taken from the proposed amended version of Regulation 1.06, Version #7, Draft #2 – Proposed, dated January 10, 2005. In Section 1 of this regulation, the District proposes to eliminate the useful and appropriate "and/or" element at line 13 and to replace it with the conjunction "and". The proposed language appears to mandate the installation, operation and maintenance of stack gas measuring, emission monitoring, **AND** parametric monitoring equipment if the owner or operator of a facility is required to put emission monitoring equipment in a stack. [Emphasis added.] Further, rather than authorizing the desirable flexibility to specify only those particular elements of a continuous emission monitoring system that are appropriate and necessary for the specific situation, the language appears to limit the District's discretion.

2. Proposed new definitions in Regulation 1.02 appear to exceed the District's statutory authority.

The statutory authority of the Clean Air Act as amended is for protection of human (or public) health and the environment. Regulation 1.02 contains at least three proposed new definitions that exceed this authority. First, the proposed new definition of "acute non-cancer effect" at line 8 speaks of "organisms" rather than humans. Second, the proposed new definition of "cancer" at line 65 addresses "mutations affecting cell growth" but remains silent as to whether the cells are human. Third, the proposed new definition of "chronic non-cancer effect" echoes the definition of "acute non-cancer effect" in its references to "organisms." If promulgated as currently worded, these proposed definitions will produce an unconstitutionally vague result, because the environmental acceptability levels and risk levels in proposed Regulations 5.20 through 5.22 are based on human health effects.

Furthermore, the proposed new definition of "welfare" at line 347 is by definition to the word "welfare" and therefore meaningless ("'Welfare' means the effects on welfare ..."). But this definition is also more seriously flawed and exceeds statutory authority. As noted above, the Clean Air Act as amended authorizes the protection of human health and the environment. "[M]an-made materials, ... weather, ... climate, damage to and deterioration of property, hazards to transportation, and effects on economic values and on personal comfort and well-being ...", are not within the direct purview of the Act. Incorporation of this proposed definition results in rulemaking beyond the authority of the District. Certainly, it could not have been intended that an industrial facility with a Title V permit or a Federally Enforceable, District Origin Operating Permit (FEDOOP) could be broadly regulated as being responsible for an individual's "personal comfort", or the pervasive heat and humidity ("weather" and "climate") recognized as typical of late summer in the Ohio River valley.

Finally, the proposed new definition of "toxic air contaminant" at line 273 includes the phrase "... and that is, or may become, harmful ...". Under this definition, any substance in the world could be classified as a "toxic air contaminant". For example, even water would be included: if there is sufficient water in the air, rain occurs and the environment is certainly harmed when the Ohio River floods its banks. This would also encompass nitrogen: Nitrogen is present in the air we all breathe, but people exposed to excessive amounts of nitrogen may get the bends or suffocate. These examples show that the proposed new definition of "toxic air contaminant" is fundamentally flawed and overly broad. The "is or may become" construction is unconstitutionally vague.

3. Proposed changes to District Regulation 1.06 are improperly drafted and vague.

The proposed amended version of Regulation 1.06, Version #7, Draft #2 – Proposed, dated January 10, 2005, is problematic in several respects. First, in Section 2, at line 28, the phrase "and in the number and frequency as prescribed by the District" is unclear. The section discusses the District's authority to require the owner or operator of a facility to "install, operate, and maintain ambient air monitoring equipment in accordance with methods prescribed by the District ...". The verb "install" matches up with "the number" but not with "the frequency". The verbs "operate" and "maintain" possibly pertain to both number and frequency, though they are more likely to match up with "the frequency". On the other hand, it is difficult to construct a meaningful sentence relating to installing ambient air monitoring equipment at any "frequency", unless the equipment is to be controlled remotely by radio transmissions.

Second, in Section 3, paragraph 3.5 is problematic. Insignificant emissions from emission points designated as insignificant activities are an appropriate additional element of the exclusions from emissions reporting requirements. For example, the amount of emissions of volatile organic chemicals (VOCs) from synthetic detergent and hot dishwater would be insignificant for such activities as washing dinner plates

and eating utensils after meals in break rooms, or cleaning glassware after use in the laboratory. However, the District's lists of trivial and insignificant activities omit this entry. Similarly, the emissions of VOC surfactants from water-based parts washers (cold cleaners) installed as direct replacements for solvent-based cold cleaners are negligible and insignificant.

Third, in Section 5, the definition of "uncontrolled emissions" in paragraph 5.1.3 is overreaching. This definition is flawed by its use of the term "air contaminant" because this term is specifically defined in District Regulation 1.02 and because all subsequent appearances of the defined term refer to a separate and distinctly different defined term. Furthermore, the definition of "uncontrolled emissions" is confusing and speculative in its language, asking that the owner or operator make at best an educated guess as to how the following language applies to their facility: " ... regardless of any enforceable limitation on the potential to emit of the process or process equipment and [regardless of] the effect of any air pollution control equipment or other process equipment that reduces emissions and that is vital to production of the normal product or to the normal operation of the process or process equipment." It is inappropriate to include such a vague definition in this regulation or to require the submittal of information derived from this definition in the associated reporting requirement.

4. Proposed Regulation 1.21 contains arbitrary and capricious leak definitions.

Proposed Regulation 1.21, Version #1, Draft #2 – Proposed, dated January 10, 2005, establishes leak definitions for the affected equipment components in Section 1, at paragraph 1.4, starting at line 30. The leak definitions for valves, flanges, pumps, agitators, compressors, and any other components generally represent reductions of 75% to 80% from equivalent leak definitions in 40 CFR Part 63, Subpart H. In establishing these local leak definitions, the District ignores the history and experience gained by the work group that assisted and provided comments to the U.S. EPA in the late 1980's and early 1990's to develop a workable equipment leak program. As a result of this effort, resolutions were reached that accounted appropriately for safety concerns associated with attempts to further reduce minor leakage from pump seals already operating at their design tolerances and stresses. These concerns are embodied in the federal regulations dealing with equipment leak detection and repair programs.

In particular, the federal leak definitions for pumps divide pump seals into three categories: general chemical service, food service, and polymerizing monomer service. The federal regulations set a leak definition of 1,000 parts per million above background for pumps handling regulated materials in general chemical service, using the equipment and methodology specified in EPA Method 21 (40 CFR Part 60, Appendix A). In addition, the federal regulations set a leak definition of 2,000 parts per million above background for pumps handling regulated materials in the food and medical service industries, presumably because such pumps would also be subject to the cleanliness standards of the federal Food and Drug Administration (FDA).

Finally, the federal regulations set a leak definition of 5,000 parts per million above background for pumps handling polymerizing monomers.

The process of developing these leak definitions as the federally enforceable Maximum Achievable Control Technology (MACT) standards for equipment leaks for the first MACT rule promulgated is summarized in the preamble to the Hazardous Organic NESHAPs proposed rule, 57 FR 62607 at 62665-62666, Thursday, December 31, 1992. Key points from this summary include the following:

- Dual mechanical seals are not suitable for use in all cases. 57 FR at 62665.
- Dual mechanical seals cannot be used with materials where leakage of the barrier fluid would affect product purity (such as with medical products), with polymerizing monomers, or on reciprocating pumps. *Id.*
- It [was] not possible to identify precisely best performance levels achievable by single mechanical seals or to predict the limits on advances in pump seal technology reasonably to be expected over the next [five] years. 57 FR at 62666.
- Because of technical limitations on the use of dual mechanical seals on pumps in food/medical service and the use of mechanical seals on pumps handling polymerizing monomers, [it was] agreed to establish separate performance standards for pumps in those two categories. *Id.*
- Pumps in general chemical service were subject to a leak definition of 1,000 parts per million above background as a performance target reflecting MACT. *Id.*
- A higher threshold of 2,000 parts per million above background was selected as the concentration at which repair is required for pumps in general chemical service, because requiring repair at lower concentrations could result in significant and costly maintenance with little or no emission reduction. *Id*

Although these concerns remain valid considerations today, the District's selection of 250 parts per million above background level as the leak definition for all pumps handling regulated substances would ignore these concerns. Accordingly, the District's proposed regulation for "enhanced" leak detection and repair is without sound basis.

A supportable approach to this issue would be to consider the fugitive emission data already collected at each facility in the District's jurisdiction that is subject to the equipment leak standards at 40 CFR Part 63, Subpart H, and to develop leak definitions for each category of pumps present at a facility on a facility-specific basis, considering the particular facility's historical records of leak detection and repair program activities.

In addition, arbitrary selection of 500 parts per million as the leak definition for undefined components is equally untenable. Components that would be subject to this leak definition include heat exchanger heads, sight glasses, meters, gauges, bolted

manways, and hatches, in addition to the undefined terms discussed in the next numbered section of these comments.

5. Proposed Regulation 1.21 contains undefined terms and language from inapplicable federal leak detection and repair standards.

The District appears to have developed proposed Regulation 1.21 by combining all of the terms and conditions found in federal equipment leak standards without regard to the applicability limitations established by the U.S. EPA for those standards. In particular, the District proposes to adopt terms from 40 CFR Part 63, Subpart RR, National Emission Standards for Individual Drain Systems. However, the first paragraph of this subpart clearly states at 40 CFR § 63.960 (a):

> These air emission standards for individual drain systems are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the other subparts that reference this subpart. [Emphasis added.]

This subpart RR is part of the Maximum Achievable Control Technology standards developed solely for facilities receiving hazardous waste from off-site locations and appropriately designated as the "Off-Site Waste and Recovery Operations (OSWRO) MACT". No other federal regulations direct any owner or operator of a facility to comply with the provisions of Subpart RR. Justification does not exist for incorporating any requirements or terms appearing in Subpart RR into proposed Regulation 1.21.

Terms from Subpart RR or elsewhere in Sections 1 and 3 of proposed Regulation 1.21 are used without providing definitions of these terms in either this proposed regulation or in proposed amendments to District Regulation 1.02, Definitions. The terms at issue include "junction box", "seal pot", "p-leg trap", "sump", "cover", "organic compound-water separator" and "process drain". The proposed regulation is vague and ambiguous because it does not provide appropriate definitions for each of these terms for the purposes of this regulation. All paragraphs containing any of these terms, singly or in combination, should be stricken from this proposed regulation.

6. Proposed Regulation 1.21 is unreasonably vague regarding the definition of "affected facility".

The proposed definition of "affected facility" is overly broad. In particular, proposed paragraph 1.1.2 would authorize the District to declare as an "affected facility" any "process unit for which the District determines the implementation of a leak detection and repair (LDAR) program is appropriate to minimize the likelihood of the occurrence of increased emissions that may become harmful to public health or welfare". [Emphasis added.] The underlined language is vague.

7. Section 14, Inorganic Compound Leak Detection and Repair, is inappropriate.

The language of Section 2, Applicability, of Proposed Regulation 1.21, Version #1, Draft #2 – Proposed, dated January 10, 2005, is awkward and confusing. It reads as follows:

> "This regulation applies to any affected facility except that an affected facility that is subject to Section 14 shall comply with the provisions of Section 14."

By thus awkwardly incorporating Section 14, leak detection requirements would be imposed for inorganic hazardous air pollutants, the focus of Section 14. However, for sound reasons, federal leak detection and repair programs generally exclude inorganic hazardous air pollutants. This exclusion exists because technology for measuring fugitive emissions of inorganic compounds does not exist in the form of commercially available instruments.

The sole exception in the federal regulations appears at 40 CFR Part 63, Subpart NNNNN, the Hydrochloric Acid Production MACT. Line 4a in Table 1 to Subpart NNNNN requires the owner or operator of an affected hydrochloric acid (HCl) production facility to "prepare and operate at all times an equipment LDAR plan that describes in detail the measures that will be put in place to detect leaks and repair them in a timely fashion." 68 FR 19075 at 19097, Thursday, April 17, 2003. We note that this requirement applies only to "equipment in HCl/Cl_2 service at existing sources." *Id.* Furthermore, the phrase "equipment in HCl service" is specifically defined to mean "each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system that contains 30 weight percent or greater of liquid HCl or 5 weight percent or greater of gaseous HCl at any time." 68 FR 19075, 19096. The phrase "equipment in chlorine (Cl_2) service" is not defined in the regulation. We would anticipate that the definition would be similar to the definition for "equipment in HCl service" with respect to the minimum weight percentages of chlorine liquid or chlorine gas that would have to be present to make the specified components subject to the equipment LDAR plan requirements. The point is that there are two, and only two, inorganic substances – hydrochloric acid and chlorine – that are subject to this LDAR requirement in all of the federal LDAR regulations.

In addition, we note that line 4b of Table 1 to Subpart NNNNN requires the owner or operator of an affected HCl production facility to "submit the [equipment LDAR] plan to the Administrator *for comment only* with [the] notification of Compliance Status". [Emphasis in original]. This language strongly suggests that the U.S. Environmental Protection Agency plans to use the submitted plans to draft revisions to the regulations containing more specificity as to how to do leak detection and repair for inorganic chemicals.

Finally, line 4c of Table 1 to Subpart NNNNN instructs the owner or operator of an affected HCl production facility that "You may incorporate by reference in such [equipment LDAR] plan existing manuals that describe the measures in place to control leaking equipment emissions required as part of other federally enforceable requirements, provided that all manuals that are incorporated by reference are submitted to the Administrator." In other words, EPA is willing to defer to any other equipment leak measures that may apply to existing HCl production facilities, if any, in lieu of developing its own standards. Given this stance at the federal level, the District cannot justify the promulgation of the proposed language of Section 14 of Regulation 1.21 with respect to such an overly broad range of inorganic chemicals.

Section 14 is overly broad. The requirement to monitor any and all components "that have the potential to leak an inorganic toxic air contaminant" is all-encompassing. The complete list of chemicals meeting the definition of "inorganic toxic air contaminant" would contain many thousands of entries. However, available ambient air monitoring data indicate that the only inorganic "chemicals of concern" in the ambient air of Metro Louisville are chromium and carbon tetrachloride. These were the only so-identified substances reported in the West Louisville Air Toxics Study (WLATS). Although emission sources of chromium and carbon tetrachloride accounting for the monitored concentrations in the WLATS have yet to be identified, there is no justification for expanding the monitoring requirements to include any other inorganic chemicals.

8. <u>There is no sound basis for specifying additional components to be monitored in proposed Regulation 1.21.</u>

Section 3, paragraph 3.1 of proposed Regulation 1.21 specifies quarterly monitoring of certain additional components not currently included in the federal leak detection and repair programs, while paragraph 3.2 purports to provide alternative monitoring schedules depending on the calculated percentage of leaks among these same components. However, the list of components in paragraph 3.1 is different from the list of components in paragraph 3.2.

The list of components in paragraph 3.1 includes agitators. The federal program already requires agitators to be monitored monthly by EPA Method 21 (a calibrated hydrocarbon analyzer). Thus, the inclusion of agitators in the list of components in paragraph 3.1 is unnecessary because it adds no environmental benefit.

Paragraph 3.1 also includes in its list the entries "cover and seal on an organic compound-water separator; and process drain." These entries are not included in the list under paragraph 3.2. Thus, the District's proposal is internally inconsistent. Sections 3.1 and 3.2 and the subsections under section 3.2 should be stricken from the proposed regulation.

9. The District has no basis for specifying an arbitrary default value for off-scale hydrocarbon analyzer results in proposed Regulation 1.21.

   Paragraph 3.6 of proposed Regulation 1.21 contains language specifying that "a default pegged value of 100,000 parts per million by volume shall be recorded" in the event that a component being monitored by a hydrocarbon gas analyzer is leaking at a rate that "pegs" the meter (i.e., exceeds the capacity of the meter). The District fails to recognize reasonable explanations for this type of situation, such as the need for recalibrating the meter for a higher concentration range and repeating the monitoring at a later time. The District also has not recognized the possibility that the hydrocarbon gas analyzer reading may represent an in-service malfunction within the analyzer, rather than an actual excessive leak situation at the component being monitored. To address a "pegging" circumstance, it would be appropriate instead to require that a facility experiencing more than some threshold number of such excessive monitoring results must notify the District and take appropriate action to investigate and report the results. Before promulgating this regulation, the District should consider its objectives more carefully and consult with the regulated community about the most appropriate way to handle this situation if and when it arises.

10. The District should define "for cause" as this phrase is used in proposed Regulation 1.21.

    Paragraph 3.8 of proposed Regulation 1.21 would authorize the District to require an affected facility to perform monitoring on a more frequent schedule than otherwise specified by proposed paragraphs 3.1 through 3.5, inclusive, "for cause" and "If the District determines that more frequent monitoring is appropriate." The community should know in advance what the conditions are that the District would consider to be "for cause."

11. The District has not provided reasonable alternatives to the requirement to repair certain leaks within one "process unit operating day".

    Section 4, paragraph 4.1 of proposed Regulation 1.21 contains language specifying that "a first attempt at repairing the leaking component shall be made no later than 1 process unit operating day after the leak is detected" for leaks identified by a hydrocarbon gas analyzer and having analyzer readings in excess of 10,000 parts per million by volume above background. This requirement is inappropriate for the following reasons:

    First, the term "process unit operating day" is not defined in this regulation or in District Regulation 1.02, Definitions. Thus, the proposed regulation is vague and unclear.

Second, as noted in Item #9 above, hydrocarbon gas analyzers may malfunction while in service; this provision makes no allowances for such malfunctions. Therefore, the regulation may mandate unnecessary repair attempts.

Third, no recognition has been made of the fact that under certain circumstances it would be impracticable or unsafe to divert personnel from their scheduled tasks to respond to a leak within one "process unit operating day". Thus, as presently drafted, the proposed requirement could create safety hazards or other unintended consequences.

Fourth, the District fails to recognize that frequently, the best repair is by outright replacement of the suspect component. However, if the replacement is not immediately available at the facility, it may need to be fabricated or purchased from an outside vendor. In such cases, the replacement may not be available within a single "process unit operating day". The regulation makes no provision for an extension of time to complete the repairs due to factors outside the facility's control.

Before promulgating this regulation, the District should consider its objectives more carefully and consult with the regulated community about the most appropriate way to require a fast response to monitored leaks.

12. Requiring "extraordinary efforts" in proposed Regulation 1.21 is inappropriate.

Sections 4.3 and 4.3.1 of proposed Regulation 1.21 contain language that reads as follows:

4.3 "For a valve that is not a pressure relief valve or automatic control valve, repair may be delayed beyond the period designated in section 4.1 only under one of the following conditions:

4.3.1 "Repair or replacement of the valve will occur at the next scheduled process unit shutdown and the owner or operator has undertaken "extraordinary efforts" to repair the leaking valve. For purposes of section 4.3, "extraordinary efforts" is defined as non-routine repair methods (e.g., sealant injection) or use of a closed-vent system to capture and control the leak by at least 90%. For a leak detected at a level greater than 10,000 ppmv, extraordinary efforts shall be undertaken within 7 days of the valve being placed on the shutdown list; however, the owner or operator may keep the leaking valve on the shutdown list only after 2 unsuccessful attempts to repair a leaking valve through extraordinary efforts, provided that the second extraordinary effort attempt is made within 15 days of the first extraordinary effort attempt. For any other leak, extraordinary efforts shall be undertaken within 15 days of the valve being placed on the shutdown list, and a second extraordinary effort attempt is not required".

This requirement is not supportable for the following reasons:

First, the term "extraordinary efforts" is defined inappropriately. It is inconceivable that our Title V facility could elect to install a "closed-vent system" – a significant process change requiring engineering design, safety reviews, etc. – in response to a determination that a particular valve was leaking. Furthermore, the performance standard for the closed-vent system – "to capture and control the leak by at least 90%" – is meaningless because it cannot be demonstrated. A leak is defined in terms of its monitored concentration around the valve, rather than in terms of its emission rate. An air pollution control device removal efficiency is normally calculated as the fraction of material entering the device that is removed from the exhaust gas leaving the device. This calculation relies on material throughput rather than a comparison of concentrations. Thus, without knowing the emission rate that corresponds to the monitored concentration for the valve, it is not possible to determine the control efficiency of the control device in the closed-vent system, or to demonstrate that the minimum removal efficiency is being achieved.

Second, the language of proposed section 4.3.1 is vague and confusing. It appears to require that a facility that makes an "extraordinary effort" at repair of a leaking valve that is not a pressure relief valve or an automatic control valve must make a second "extraordinary effort" regardless of the success or failure of the first attempt. This is so because the paragraph does not define a successful outcome of an "extraordinary effort".

Third, the District should not be inserting itself into mandating repairs in this regulation. The District lacks the experience and knowledge of industrial production operations necessary to evaluate a facility's evaluation of the safety, mechanical, or environmental concerns associated with the implementation of "extraordinary efforts" at leak repair. Multiple hazards could be associated with conducting non-routine "extraordinary efforts" involving a multitude of valves. Thus, this proposed regulatory section should not be adopted without consideration of these safety considerations.

Before promulgating this regulation, the District should consider its objectives more carefully and consult with the regulated community about the most appropriate way to accomplish them.

13. Requiring a supervisory-level person to "sign off" on putting a component on a "delay of repair" list is inappropriate.

Paragraph 4.4 of proposed Regulation 1.21 inappropriately requires a facility supervisor (another undefined term) to authorize the listing of a component for delay of repair. This provision is inconsistent with proposed Section 6 of this regulation, which requires the facility to establish a leak detection and repair (LDAR) [program] coordinator who "shall be authorized to implement" appropriate changes regarding

leak detection and repair activities. The LDAR coordinator should be authorized to add a component to the delay of repair list without regard to whether the person assigned as the facility LDAR coordinator occupies a supervisory role.

14. There is no accommodation made for difficult-to-monitor and unsafe-to-monitor components throughout proposed Regulation 1.21.

    In particular, proposed Regulation 1.21 would apply to affected facilities additional requirements beyond the basic requirements of 40 CFR Part 63, Subpart H, as indicated by the introductory paragraph of proposed Section 3 at lines 56-57. Section 3 omits any language acknowledging that the additional requirements may apply to components that qualify as "difficult to monitor" or "unsafe to monitor", as those terms are defined and used in Subpart H. This omission is a serious practical defect in the proposed regulation that the District must remedy before promulgation.

15. Prohibiting a "new or reworked" underground process unit pipeline from containing a buried valve is inappropriate.

    Section 5.5 of proposed Regulation 1.21 establishes this prohibition. The District lacks the fundamental engineering knowledge and experience to be involved in regulating the design parameters for underground pipelines. In addition, the term "reworked" is not defined in this regulation or elsewhere in the District's regulations.

16. Prohibiting screwed connections in "new piping larger than 2 inches in diameter" is inappropriate.

    Section 5.7 of proposed Regulation 1.21 establishes this prohibition. The District lacks the fundamental engineering knowledge and experience to be involved in regulating the design parameters for process piping. In addition, most manufacturers of industrial process equipment are not located in Louisville Metro/Jefferson County, Kentucky. Thus, the District is unable to establish this regulatory requirement as a practical matter.

17. Requiring the facility owner or operator to assess the training of contractors hired to perform leak detection and repair program activities.

    Section 6 of proposed Regulation 1.21 sets forth this requirement at paragraph 6.3 (" ... the owner or operator shall determine and assure that the contracted employees have sufficient training to meet the requirements of this section.") Requiring a facility that hires contractors to "determine and assure that the contracted employees have sufficient training" is unnecessary and redundant.

18. Necessary exemptions from Section 8 of proposed Regulation 1.21 have been omitted.

Regulation 1.21 omits the following key exemptions from the federal leak detection and repair standard codified at 40 CFR Part 63, Subpart H:

- Equipment in otherwise regulated service that operates less than 300 hours per year, as provided by 40 CFR §§ 63.160(a) and 63.162(e).
- Equipment in otherwise regulated service in research and development facilities or bench-scale batch processes, as provided by 40 CFR § 63.160(f).
- Equipment containing less than 5 percent by weight of total organic hazardous air pollutants or less than 10 percent by weight of volatile organic compounds, as provided by the definitions of "in organic hazardous air pollutant service" and "in volatile organic compound service" in 40 CFR § 63.161, or an equivalent cutoff concentration for equipment in inorganic toxic air contaminant service (a term not defined in proposed Regulation 1.21 or elsewhere in the District's regulations).
- Clarifications of the definition of "process unit shutdown" at 40 CFR § 63.161, consisting of the following language: "An unscheduled work practice or operational procedure that stops production from a process unit or part of a process unit for less than 24 hours is not a process unit shutdown. An unscheduled work practice or operational procedure that would stop production from a process unit or part of a process unit for a shorter period of time than would be required to clear the process unit or part of the process unit of materials and start up the unit, and would result in greater emissions than delay of repair of leaking components until the next scheduled process unit shutdown, is not a process unit shutdown. The use of spare equipment and technically feasible bypassing of equipment without stopping production are not process unit shutdowns."
- Open-ended valves or lines containing materials which would auto-catalytically polymerize, or would present an explosion, serious overpressure, or other safety hazard if capped or equipped with a double block and bleed system as specified in 40 CFR §§ 63.167(a) through (c), as provided by 40 CFR § 63.167(e).
- Connectors that are inaccessible or ceramic or ceramic-lined, as provided by 40 CFR § 63.174(h)(1) and additional subsections defining inaccessibility of connectors for reasons other than being buried or insulated, as provided by 40 CFR §§ (h)(1)(iii) through (h)(1)(vi), inclusive. We note that paragraph 8.2.3 of proposed Regulation 1.21 contains appropriate exemptions for buried or insulated connectors and urge that these exemptions be preserved.

19. The District proposal to require data review plans in Section 11 of proposed Regulation 1.21 is inappropriate for facilities using contractors to perform leak detection and repair program activities.

    The District fails to recognize that the items listed under Section 11 of proposed Regulation 1.21 – namely, the number of components monitored per technician, the times between monitoring events, and the presence of "abnormal" data patterns – go to the heart of the skills for which leak detection and repair program contractors perform their work. Section 11 omits the reasonable alternative of documenting the contracting company's requirements for its employees with respect to these fundamental skills as satisfying the affected facility's requirement to prepare a data review plan.

20. Requiring periodic independent third-party audits of leak detection and repair program activities at affected facilities.

    DuPont Dow Elastomers continues to believe that the District and/or the U.S. EPA should perform the functions specified in Section 12 of proposed Regulation 1.21. We note that this option is provided in paragraph 12.4. While the alternative compliance option set forth at paragraph 12.5 is commendable in terms of the District's willingness to provide much-needed flexibility to affected facilities, it remains our view that the obligations of independently auditing these programs belong squarely and solely to the permitting and enforcement authorities.

21. The District's requirements for preparation, submittal, and implementation upon District approval of a leak detection and repair plan is burdensome, duplicative of existing recordkeeping and reporting requirements for affected facilities already subject to the federal Subpart H requirements, and duplicative of requirements within proposed Regulation 1.21.

    Facilities that have been subject to the regulatory requirements of 40 CFR Part 63, Subpart H, are already subject to extensive recordkeeping requirements at 40 CFR § 63.181 and sequential and periodic reporting requirements at 40 CFR § 63.182. The requirements of Section 13 of proposed Regulation 1.21 duplicate these pre-existing requirements. The District should exempt facilities already subject to 40 CFR Part 63, Subpart H from any requirements other than to maintain necessary records and have the records for inspection upon request.

    In addition, the particular requirement of proposed paragraph 13.1.8 to submit a data review plan is duplicative of the identical requirement in proposed Section 11 of this regulation. Therefore, either proposed paragraph 13.1.8 or the introductory language to proposed Section 11 is redundant and should be eliminated.

    The requirement to prepare and submit a leak detection and repair plan to the District within 120 days of promulgation of proposed Regulation 1.21, as provided in

proposed section 13.2 for affected facilities already subject to a federal leak detection and repair program, is unsound. There is no rational basis for determining that 120 days is an adequate amount of time to prepare such a plan, or that 60 days is an adequate time period in which to make revisions to the plan in response to the District's determination of the existence of a deficiency.

22. An exemption should be provided from either this particular requirement or from this proposed regulation as a whole for facilities that to close.

Proposed Regulation 5.20

General

1. U.S. EPA's Risk Characterization Handbook (U.S. EPA, 2000) defines four qualities of an effective risk characterization as transparency, clarity, consistency and reasonableness. Effective regulations that incorporate risk assessment as a component should possess these same qualities. The Proposed Regulations Sections 5.20, 5.21 and 5.22, in their present form, are deficient in all four categories. Specific examples of these deficiencies and recommended changes are provided below.

Sections 1 and 2

2. Section 1 grants unduly broad discretion to the District to make determinations on risk for which required skills and experience in toxicology and risk assessment are required. The District does not possess the requisite capabilities and scientifically qualified staff to perform an adequate job of deriving scientifically-justifiable BAC values. A scientifically sound methodology for making such determinations should be developed through a consensus approach with the regulated community and recognized scientific experts and be a part of any final regulation. There are recognized experts on chloroprene, for example, who would need to be consulted during the process of establishing BAC values for chloroprene.

3. Section 2.1: The hierarchy for determining whether a compound is a carcinogen (as addressed in Section 2) is flawed by excluding other agencies such as the U.S. EPA and California OEHHA. DuPont Dow believes that the hierarchy should be: (1) IRIS, (2) NTP, (3) IARC, and (4) OEHHA. These agencies and organizations have specific regulatory mandates, personnel and expertise to classify substances for potential human carcinogenicity. Section 3.3 should be changed to reflect this hierarchy as well.

4. Sections 2.1.4-2.1.4.2.3: Without the technical expertise to understand and apply these guidelines, these sections will be subjective and arbitrary, and should be removed. If the hierarchy as discussed in Comment 3, above is not utilized to determine the appropriate cancer classification, the District cannot possibly make a valid scientific determination of carcinogenicity, since it does have the necessary

toxicological knowledge and experience to do so. The basis for determination of carcinogenicity must be the hierarchy described under Section 2.1.1.

5. Section 2.2-2.2.2: This discussion is vague and creates additional uncertainty in the regulated community. We believe the basis for determination of carcinogenicity must be the hierarchy proposed in Comment 3. Before the District could decide to classify for itself based on section 2.1.4, numerous supplemental criteria must be addressed to ensure that high quality studies are used in the assessment.

   For example, data to be used as the basis for BAC_C development should meet the following minimal essential criteria:

   - Inhalation studies should be used preferentially as the basis; cancer studies by other routes of exposure should not be used unless clear evidence exists that portal of entry (i.e., respiratory tract) effects do not occur or that the lung is critical to the metabolic disposition and toxicological properties of the substance.
   - Studies should be well-documented (ideally conducted by good laboratory practices) using established protocols, have adequate description of historical control responses and be published in peer-reviewed scientific literature.
   - Where human epidemiology data exists and conflicts with animal data, as in the case of chloroprene, modifications to the URE should be permissible, using human data preferentially.
   - Where sufficient mechanistic data exists to show that a deviation from linear dose response exists, application of threshold-based, non-linear risk assessment approaches (margin of exposure approach) should be acceptable.
   - The newest toxicological data should be used for URE evaluation. URE based on obsolete data or risk assessment approaches should be reassessed with the newest data.

Section 3

6. Section 3.1: The basis for the universal use of 10^{-6} risk is inconsistent with EPA's methodology, and no scientific justification for the higher level of stringency has been established. The District's proposal is unduly stringent, applied only to fixed facilities, and arbitrary and capricious. It should be changed to be consistent with the U.S. EPA methodology described below.

7. A $1x10^{-6}$ risk is typically used for "screening purposes" as a target risk level. However, with respect to making risk management decisions, a range of target risks $1x10^{-4}$ to $1x10^{-6}$ is typically used, based upon past regulatory experience (Travis and Hattemer-Frey, 1988). For example, in response to the 1987 vinyl chloride Clean Air Act § 112 decision (NRDC, 1987), U.S. EPA decided it would base its regulatory decision on quantitative risk assessment using the general policy that the lifetime added cancer risk for the most exposed person of 1 in 10,000 (1×10^{-4}) might constitute acceptable risk and that the margin of safety required by statute and

reinforced by the court should reduce the risk for greatest number of persons to an individual added lifetime risk of no more than one in one million (1×10^{-6}). The U.S. EPA has repeatedly rejected the opinion that it can establish a universal (*i.e.*, brightline) acceptable risk that should never be exceeded under any circumstances, and that guidance provided under one statute may have little relevance to others because of program goals and objectives. It is difficult to conceive how the District Air Board proposes to improve on the scientific state of the knowledge.

8. Section 3.3: The proposed regulation lists a hierarchy of three regulatory agencies (U.S. EPA, OEHHA and Michigan), as references for BAC_C development. A single methodology is desirable to avoid confusion and to ensure consistency. We recommend that the method used for IRIS is preferable among the three approaches. Several secondary approaches (some no longer current) are referenced should no BAC_C exist from any of the three agencies. A primary problem with this hierarchical approach is that these agencies may apply different criteria, rely on different critical studies, apply different dose response models, and use different points of departure in their risk characterization. Consequently, three different URE may be identified by the three agencies (See comments for 3.3.2 and 3.3.3). This is problematic since specific criteria are not included that would identify a single URE in case multiple URE existed.

   When multiple values are available for a chemical, the lowest value should not be selected as a matter of default for the sake of conservatism. In addition, use of a composite value (mean or geometric mean of several possible BAC values) is not recommended. Rather, several factors should be considered, including (1) date of the assessment; (2) appropriateness and consistency of the methods used; and (3) critical assumptions made.

   The potential availability of different URE values from the different agencies could be eliminated if a single agency and its approach were used exclusively. Given the broad list of substances already evaluated and its established protocol, the U.S. EPA IRIS approach described in chapter 12 of the FERA Air Toxics Risk Assessment Reference Library Technical Resource Manual should be used for all URE determinations.

9. Section 3.3.1: The date of the IRIS assessment must be considered when selecting an appropriate URE or RfC value (see parts 3.3.1 and 4.1). While U.S. EPA's IRIS database is often cited as the first-tier source for chronic toxicity values for human health risk assessment, the information it contains is not always current. Additionally, if U.S. EPA's current methods for cancer and non-cancer dose-response assessment (U.S. EPA, 1999; 2002; 2003; 2004) are adopted as the "standard" for risk assessment, then up-to-date values derived by these methods should be adopted over values derived by other methods.

10. Sections 3.3.2 and 3.3.3: The CA and MI lists should be removed from the hierarchy used to determine URE. Methods used by the California Office of Environmental

Health Hazard Assessment (OEHHA) and the Michigan Department of Environmental Quality (DEQ) differ from current U.S. EPA methods, and in many ways resemble U.S. EPA methods as they were prior to method changes in 1992 and 1996. For example, both California and Michigan use an allometric scaling factor of 0.67 compared to a value of 0.75 (U.S. EPA, 1992) to extrapolate equivalent doses from animal studies to humans. This difference alone can result in URE values that are more than 50% and 85% larger than is supported when based upon rat and mouse studies, respectively. Another important difference is that both OEHHA and DEQ estimate the slope of cancer dose-response relationship using the upper 95% confidence limit in the linear term (q1* value) as predicted by the linearized multistage model. Under current U.S. EPA guidelines (U.S. EPA, 1996; 1999; 2003), the q1* is no longer used, but instead the slope is estimating by linear extrapolation from a point of departure [*e.g.,* the dose corresponding to a 10% increase in extra risk (ED10) and its lower confidence limit (LED10)]. Reliance upon the q1* can significantly overestimate the cancer slope factor since the lower bound (on dose) fit of linearized multistage model has a tendency to predict supralinear curves, even in cases when there is no information to suggest that the dose-response relationship is truly supralinear. The extent to which the q1* overestimates the cancer slope factor will vary from chemical to chemical. Finally, both California and Michigan adjust their cancer potency estimates by a factor of (animal exposure duration/animal life expectancy)^3 when less-than-lifetime animal studies are used as the basis. The U.S. EPA does not practice this approach (1996, 1999, 2003). For example, when a one-year rodent study serves as the basis of cancer potency, this adjustment would increase the URE value by a factor of 8 without a consideration of the underlying mode of action. For these reasons and to avoid confusion and inconsistencies in BAC_C values, we believe that OEHHA (section 3.3.2) and DEC (sections 3.3.3 and 3.3.4.4) values should be removed from the hierarchical approach used for URE.

11. Section 3.3.5: <u>The scientific basis for the default value of 0.0004 ug/m^3 is not transparent or specified. In the absence of animal bioassay data, the cancer potency equivalent to this default is highly questionable. Application of a default value without scientific justification misleads the public about actual risk.</u> Thus, utilization of this value would be arbitrary and capricious. If a BAC_C cannot be established from existing scientific data, then the District should not assess carcinogenic risk.

12. Section 3.4: <u>There is no logical connection between the underlying source of the BAC value and the method for estimating the maximum ambient concentration from emission rates.</u> A specification is made for use of "average time period." It is unclear from the proposed rule precisely to what this term is referring or what role it is expected to play. All of the benchmark ambient concentration (BAC) methods in these sections, regardless of whether the underlying basis is an unit risk estimate (URE), reference concentration (RfC), reference dose (RfD), occupational exposure limit (OEL), or acute toxicity value, adjust for differences in exposure time, frequency, and duration, and therefore, the resulting BAC values are protective for lifetime, continuous exposures.

13. Section 3.4: There is no justification provided for use of an annual averaging time for cancer. This might mask effects attributable to peak exposures.

Section 4

14. Several methods are specified. Some of these methods are unjustifiable scientifically and contradict risk characterization guidance given by EPA for non-cancer endpoints. This District would be better served by implementing a single approach based on repeated dose animal studies (e.g., chapter 12 of the FERA Air Toxics Risk Assessment Reference Library Technical Resource Manual), minimally of 4 wks duration. To this end, sections 4.2 and greater should be deleted. In addition, DuPont Dow offers the following specific comments:

15. As described in comments for BAC_C for section 2.2, data to be used as the basis for BAC_{NC} determinations are not adequately defined. Data should meet the following minimum essential criteria:

    - Studies should use inhalation as the route of exposure.
    - Studies should be based on durations of either 4 or 13 wks of duration. Shorter duration exposures are less reliable and impose additional uncertainty factors to extrapolate short term-effects to chronic-effects.
    - Endpoints cited should be based on toxicologically adverse effects; statistically significant effects need to be interpreted opposite biological significance.
    - Studies should be well documented, conducted by good laboratory practices using established protocols, and be published in peer-reviewed scientific literature.

16. Section 4.2: The application of different methodologies, such as California's REL, would likely jeopardize the consistency of the BAC values derived from the EPA methodology. California's methods for deriving recommended exposure limit (REL) values may differ from U.S. EPA's methods for deriving RfC values. For example, these two agencies may apply different uncertainty factor values, particularly for database deficiencies, to the same no-observed-adverse-effect-level (NOAEL) value, such that the resulting safe concentration values differ by as much as a factor of 10.

17. Section 4.3: This section is inappropriate and should be removed. Oral or dermal data should not be used to determine BAC_{NC} where inhalation is the primary route of exposure. As noted in 4.12, oral to inhalation extrapolation should only be done where previous data exists to show that oral to inhalation BAC_{NC} determination can be justified. Although the method presented represents the default approach used by U.S. EPA and other agencies for a number of years, it requires a careful consideration of two important factors that can complicate this extrapolation: (1) it should be determined if the effect of interest is a systemic effect or a point-of-contact (i.e., nasal or respiratory tract) effect. While extrapolation of the former may be appropriate, extrapolation of the latter is not advised; and (2) it should be determined if there is a

"first-pass" metabolism effect in the liver or the lung. If either is expected, more sophisticated methods for extrapolation, such as physiologically based pharmacokinetic (PBPK) modeling may be required.

18. Section 4.3: Although default values of 70 kg and 20 m^3/day have been used in the past for the purposed of extrapolating toxicity criteria across routes of exposure, they are not supported by the best available data. U.S. EPA's exposure factors handbook (U.S. EPA, 1999) recommends values of 71.8 kg (average for adult men and women) and 13.3 m^3/day (average of 11.3 and 15.2 m^3/day). Continued use of the unsupported default values results in BAC_{NC} values that are conservative by more than 50%. This section should be changed to be consistent with the EPA values.

19. Section 4.4-4.11: These sections should be removed for reasons repeatedly stated throughout these comments. The District is not technically qualified to make these determinations.

20. Section 4.5: It is inappropriate to use OSHA or TLV occupational exposure limits as the basis for the community BAC_{NC}. The OSHA and TLV are intended to protect workers from adverse health effects; this is interpreted to encompass all adverse health effects, including cancer. Thus, the definition of BAC_{NC} becomes confused when the OEL is based on cancer and non-cancer endpoints.

    Additionally, the need to adjust OEL values for differences in exposure duration and time needs also to take into account the mode of action by which the adverse effect is produced. For endpoints that are attributable to peak concentrations, such as respiratory irritation, this adjustment may not be necessary and would result in BAC_{NC} values that are unnecessarily restrictive by a factor of up to 100.

    Collectively, these issues again suggest that a single approach, recommended in our general comments on Section 4 should be used for BAC_{NC}.

21. Section 4.6: The use of multiple uncertainty factors described in this section by incorporating results from short-term studies renders the derived BAC_{NC} value meaningless since the composite uncertainty is so large, it is of questionable value.

22. Sections 4.6 - 4.10: The justification for use of short-term or acute studies in setting BAC values is not documented, and is not supported by U.S. EPA and other authoritative bodies.

    Although approaches on the use of short-term or acute toxicity data in human health risk assessments for chronic exposures have been published in the past (Venman and Flaga, 1985; Layton et al., 1987), their application in a regulatory setting is neither prudent nor reasonable for current risk assessment practices. The net uncertainty factors in these sections of the proposed rule range from 3,500 deriving RfD and RfC values (U.S. EPA, 2002) and by OEHHA (to 2,000,000 far exceed the maximum value of 3,000 adopted by U.S. EPA for OEHHA, 2000). Such large values do not

appear to recognize the considerable overlap between the various adjustments and uncertainty factors, and as such are expected to result in BAC values that are unnecessarily restrictive and unrealistic.

Emphasis should be placed on using high quality chronic and sub-chronic rather than using the results of studies that use a 7-day (an atypical duration since most studies are 2, 4 or 13-wk duration) or shorter exposure duration. Chemicals that lack even a single sub-chronic or chronic toxicity studies do not meet the minimum database requirements for conducting a human health risk assessment for human health (U.S. EPA, 2002).

23. Sections 4.8-4.11: As noted above, there is no scientifically justifiable basis for determining inhalation BAC_{NC} based on acute lethality data. There is no established relationship between lethality and what might prove to be selective effects on organ systems (e.g., reproductive function) resulting from cumulative, low level exposure. The introduction of such large uncertainty (with factors totaling up to 2,000,000) yields essentially meaningless BAC_{NC} values. For this reason, in cases where repeated inhalation data do not exist, a BAC_{NC} should not be determined.

24. Section 4.11: The basis for the default value of 0.04 ug/m^3 is not transparent or specified, and thus is arbitrary and capricious. In the absence of animal bioassay date, the non-cancer BAC equivalent to this default misleads the public about actual risk. If a BAC_C cannot be established from existing repeated exposure animal bioassay data, then non-carcinogenic risks should not be assessed.

25. Section 4.12: Here and elsewhere in section 4, a specification is made for use of "average time period." It is unclear from the proposed rule precisely to what this term is referring or what role it is expected to play. All of the benchmark ambient concentration (BAC) methods in these sections, regardless of whether the underlying basis is an unit risk estimate (URE), reference concentration (RfC), reference dose (RfD), occupational exposure limit (OEL), or acute toxicity value, adjust for differences in exposure time, frequency, and duration, and therefore, the resulting BAC values are protective for lifetime, continuous exposures.

    However, in some cases an annual average time is recommended, while in other cases a 24-hour average time is recommended or an 8-hour average time is recommended. The "average time" may be related to Table 1 of Section 2.2 for Proposed Regulation 5.22. However, since BAC values are protective of lifetime, continuous exposures, there does not appear to be a logical connection between the underlying source of the BAC value and the method for estimating the maximum ambient concentration from emission rates. Some additional explanation, clarification, and revision of the methods is required regarding the use of the term "average time period."

26. Section 5: This section should be removed. If methodologies as recommended above do not developed a BAC_{NC}, the District does not have the capability of making this scientific determination.

Proposed Regulation 5.21

1. Section 1: The terms "goal" and "standard" are undefined, making this section vague. In addition, the broad discretionary power granted to the District to make determinations for which they are not scientifically-qualified adds uncertainty to the regulated community and is arbitrary and capricious.

2. Section 1.51-1.53: The four-tier structure is unnecessarily broad and overreaching, adds 188 chemicals not identified as significant risks, and is therefore an arbitrary and capricious addition to these regulations. It should be simplified (see comments on 5.23).

3. Section 2.2: The environmentally acceptable level for a carcinogen (EALc) values specified in the table range from 1.0 to 3.8. Although the value of 1.0 is recognized as corresponding to a default *de minimis* risk of $1x10^{-6}$, it is unclear precisely how the value of 3.8 (corresponding to a risk level of $3.8x10^{-6}$) was determined as a "goal." Some additional explanation and derivation of this goal is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable.

4. Section 2.2: By summing EAL values across toxic air contaminants (TACs) as defined by the District, a hidden conservatism is introduced by summing upper-bound estimates of risk. Summing the central tendency estimates of risk across TACs provides a more appropriate estimate of the combined risk.

5. Section 2.2: The environmental acceptable level for non-carcinogens (EALnc) values specified in the table ranges from 0.2 to 0.38. These values are less than the target hazard quotient (HQ) of 1.0 typically used in non-cancer risk assessment, and it is unclear how these values were determined as "goals". Additional explanation and justification of these goals is required. A margin-of-safety approach (*i.e.*, evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints.

6. Section 2.5: The EALc values specified in the table range from 1.0 to 7.5. Although the value of 1.0 is recognized as corresponding to a default *de minimis* risk of $1x10^{-6}$, it is unclear precisely how the value of 7.5 (corresponding to a risk level of $7.5x10^{-6}$) was determined as a "standard." Some additional explanation and derivation of this standard is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable.

7. Section 2.5: By summing EAL values across TACs, a hidden conservatism is introduced by summing upper-bound estimates of risk. Consideration should be given to summing the central tendency estimates of risk across TACs to provide a more appropriate estimate of the combined risk.

8. Section 2.5: The EAL_{NC} values specified in the table ranges from 0.2 to 0.75. These values are less than the target HQ of 1.0 typically used in non-cancer risk assessment, and it is unclear precisely how these values were determined as "goals" and "standards." Some additional explanation and derivation of these values is required. A margin-of-safety approach (*i.e.,* evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints.

9. Section 2.8: It is unclear how the value of 10 (corresponding to a risk level of $1.0x10^{-5}$) was determined as a "goal." Additional explanation and justification of this goal is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.,* $1x10^{-6}$ to $1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable.

10. Section 2.8: By summing EAL values across TACs, a hidden conservatism is introduced by summing upper-bound estimates of risk. Consideration should be given to summing the central tendency estimates of risk across TACs to provide a more appropriate estimate of the combined risk.

    A margin-of-safety approach (*i.e.,* evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints.

11. Section 4.10: This section deals with additivity of response that could affect the EAL. There is comparatively little data to justify quantitative adjustments for EAL on cancer or noncancer effects. At a minimum, there should be very clear guidance on what constitutes the minimal core data needed that could imply a relationship for additive effects. This guidance must consider whether the mechanism of action is comparable and whether the same target organs are involved. Conversely, if guidance on additive effects is included in a revised procedure, then the procedure should allow adjustments in the opposite direction if the scientific data could support antagonistic interactions of different substances.

Proposed Regulation 5.22

1. Sections 2.2 & 3.8: As indicated in comment to Proposed Regulation 5.20, Section 3 through 4, the term "averaging time" is not transparent, and its application here may not be appropriate. All of the BAC values derived by the methods described in proposed regulation have been adjusted for differences in exposure time, frequency, and duration. Therefore, these values are protective of lifetime, continuous exposures. As such, these values should only be compared to an appropriate average concentration (*e.g.*, arithmetic mean and 95% upper confidence limit) that might be encountered during chronic or lifetime exposures. The factors listed in Tables 1 and 2 are not documented along with any underlying assumptions. Therefore, it is not possible to determine if their application to the corresponding emission rates will result in concentrations at the point of exposure that are appropriate for a chronic duration.

Proposed Regulation 5.23

1. The West Louisville Air Toxics Study (WLATS) risk assessment was based on monitoring for specific chemicals on the TO-15 list of analytes plus several other additional chemicals. The measurements of the volatile and semi-volatile organics on the list of analytes were subject to round-robin comparisons between the three participating laboratories (U of L Air Quality Lab, Kentucky Division of Environmental Services, and the U.S. EPA's lab at Athens, Georgia). Accordingly, there was an ongoing quality control and quality assurance program that kept these measurements within acceptable error ranges of each other. However, the U.S. EPA lab was the only site that performed analyses for metals and reactive aerosols. There was no quality control and quality assurance program for their analyses. Accordingly, the risk assessment report's conclusions leading to the inclusion of arsenic, cadmium, and nickel as chemicals of potential concern are questionable at best.

2. The inclusion of categorical entries such as "arsenic and arsenic compounds" in the Category 1 and Category 1A lists is unjustified and inappropriate. The normal analytical method for metal compounds is atomic absorption (AA). This method cannot identify the compound or compounds that contain the metal as part of its structure. It is fundamentally unscientific to treat all compounds that contain a metal as part of its structure as having the same degree of risk as the parent metal.

3. Chromium is identified as a special case in the risk assessment. It is acknowledged by the study's authors that the "risk" associated with chromium is based on the highly questionable assumption that the chromium metal was in the form of the hexavalent chromium ion. Atomic absorption cannot distinguish between hexavalent chromium and the significantly less toxic trivalent chromium. The chromium results in the risk assessment report do not justify the inclusion of all compounds containing chromium in the Category 1 list without more investigation by the Louisville Metro Air

Pollution Control District into the sources of chromium emissions in the community. Only compounds containing hexavalent chromium should be regulated as air toxics under this program.

4. *De minimis* emissions should be exempted.

5. Addressing toxic air pollution in Louisville Metro would require the District to consider listing environmental tobacco smoke (secondhand smoke) as a pollutant requiring control in restaurants, public buildings, etc.

6. It is unfair for the District to draft a regulation requiring the reporting of TAC emissions by July 15, 2005 for all of calendar 2004, when facilities in the District's jurisdiction have not had any forewarning that they would need to collect appropriate data supporting these calculations until mid-September of the year, and any final regulation may not be promulgated until December at the earliest.

   The U.S. EPA commonly allows facilities at least a full calendar year's notice when adding chemicals or chemical categories to the Toxic Release Inventory list at 40 CFR Part 372. This practice accounts for the fact that the TRI reports due by July 1 of each year are for the estimated releases of listed chemicals during the entire preceding calendar year (the "reporting year".)

7. The number of chemicals affected by this regulation has been inaccurately characterized. We hear constant references to "the list of 18" or "the list of 20". This characterization obscures the facts. There are 18 entries in the District's list of "Category 1 Toxic Air Contaminants". Only 14 of these are individual chemicals. According to the on-line Combined Chemical Dictionary (Copyright 1982-2004 Chapman & Hall/CRC Press), there are at least 3,724 chemicals that contain arsenic as part of their chemical structure. (See table below.) No attempt was made to avoid double-counting compounds that may belong to more than one chemical category, since the draft regulations are completely silent on how to handle such compounds.

Preliminary Regulatory Impact Assessment

1. The intention of the WLATS was to monitor for concentrations of chemicals, conduct a Risk Assessment at a screening level, and then implement a Risk Management Plan that included significant community interaction in developing risk reduction strategies. The approach taken by the District has circumvented that process. It is incorrect to use the results of the WLATS study as a blanket justification for this set of proposed regulations.

2. The Preliminary Regulatory Impact assessment fails to address the fact that many of the chemicals it proposes to regulate to extremely low levels are present in areas of Jefferson County that are not near regulated sources.

3. Approximately 1/3 of TRI air emissions in Jefferson County are reported by companies that are most affected by this set of proposed regulations. The remaining air emissions, which constitute the strong majority of total community risk, are unaddressed or will not be addressed until much later.

4. The District does not make a case for the necessity of regulations that are extreme in nature as applied to chemical plants, nor does it make a case for excluding many other sources of risk that create the vast majority of community risk.

5. The District consistently underestimates the impact of these regulations on the regulated community.

   DuPont Dow believes that the LDAR changes as proposed will require up to a 100% increase in resources required to administer the program, rather than the 25% increase estimated by the District.

   The District significantly underestimates the cost and effort for modeling. With the parameters proposed in these regulations, it is expected that DuPont Dow would need to conduct even more complex and expensive monitoring than Level 4. Our experience with other types of risk modeling indicates that the actual effort required will be as much as 10x that estimated by the District.

   The costs of control strategies addressed by the District far under-estimate actual anticipated costs. For DuPont Dow Elastomers, as estimated in 2004, the minimum capital cost of the next potential emission reduction would be $35,000 per ton. Additional emission reduction projects approach $150,000 per ton. Both values far exceed the $20,000 per ton used in the Preliminary Regulatory Impact Assessment issued by the District and implied as an upper bound.

   The District significantly understates the incremental cost and effort for applying for a new construction permit under the proposed regulations vs. current regulations, both for modeling time and engineering time.

6. The District creates the impression of a collaborative process with involvement by a large number of people with all its public meetings during the informal comment process. However, since many of the same people in the regulated community and the community at large attended numerous meetings, the actual number of people involved in that process is much smaller than implied. In fact, those meetings were the only interaction allowed by the District, since the proposed regulatory package and the minor revisions made in the final proposed regulations was done with no stakeholder input whatsoever.

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